510(k) Summary

MAY 27 2009

Sponsor: Alcavis International
8322 Helgerman Court
Gaithersburg, MD 20877

Contact Person: Gary J. Mishkin
Vice President, Research and Development
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Date Prepared: September 25, 2008

Device Name: Proprietary Name: ExSept WC Skin and Wound Cleanser
Common Name: Wound Cleanser
Classification Name: Dressing, Wound, Drug

Predicate Devices: ExSept WC Wound Cleaner, K061467
SilvaKlenz Skin and Wound Cleanser, K063069
Dermacyn Wound Cleanser, K042729
Anasept Animicrobial Skin and Wound Cleanser, K073547

Device Description: ExSept WC Skin and Wound Cleanser is a clear to slight yellow, slight chlorine odor, solution which is intended for the mechanical cleansing of debris and foreign material from exudating/dirty epidermal and dermal wounds. It is supplied in a 200 ml pump-spray and 100 ml, 250 ml and 500 ml pour bottles. ExSept WC Skin and Wound Cleanser has a 30 month shelf life.

Intended Use:

OTC: ExSept WC Skin and Wound Cleanser is intended for cleansing and removal of dirt, debris and foreign material from minor skin abrasions, minor lacerations, minor irritations, minor cuts, and intact skin.

Professional Use: Under supervision of healthcare professionals, ExSept WC Skin and Wound Cleanser is intended for use for mechanical cleansing, debridement and removal of foreign material and debris from exudating and/or dirty wounds, such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites, and catheter exit sites.

Substantial Equivalence: ExSept WC Skin and Wound Cleanser is substantially equivalent in the cleansing functions and intended uses to the predicate devices ExSept WC, SilvaKlenz, Dermacyn

and Anasept. All predicate devices use a mechanical action to remove foreign material and other debris from the wounds and surrounding skin.

Testing: Numerous in-vitro and in-vivo studies have been performed to demonstrate the efficacy, safety and biocompatibility of the ExSept WC Skin and Wound Cleanser for the indications for use. Stability studies show a shelf life of 30 months for the ExSept WC Skin and Wound Cleanser, when stored at room temperature.

Conclusion: Based upon the information in the 510(k) submission, ExSept WC Skin and Wound Cleanser will perform as intended as a wound cleanser. ExSept WC Skin and Wound Cleanser is substantially equivalent in its actions and functions as the marketed devices ExSept WC, SilvaKlenz, Dermacyn and Anasept.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Alcavis International, Incorporated
% Mr. Gary J. Mishkin
Vice President, Research and Development
8322 Helgerman Court
Gaithersburg, Maryland 20877

Re: K082858
Trade/Device Name: ExSept WC Skin and Wound Cleanser
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: II
Product Code: FQH
Dated: April 17, 2009
Received: April 20, 2009

Dear Mr. Mishkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

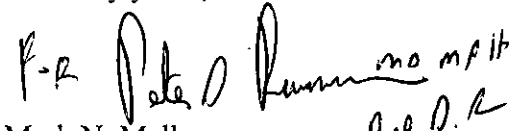
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K082858

Device Name: ExSept WC Skin and Wound Cleanser

Indications For Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K062656